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APPLICATION NO.	FILING DATE	I FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,497	09/28/2001	Harry S. Sowden	MCP-294	5321
27777	7590	12/14/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ORTIZ, ANGELA Y	
ART UNIT		PAPER NUMBER		1732

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/966,497	SOWDEN ET AL.
	Examiner Angela Ortiz	Art Unit 1732

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 07 November 2005.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-12, 14-22 and 137 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-12, 14-22 and 137 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 28 September 2001 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

The amendment filed November 7, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 1 and 21 newly claim a nozzle in direct engagement with a molding chamber; such is not supported.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 14-22, 137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant newly claims a nozzle in 'direct engagement with a molding chamber' and cites page 10 for support; however no such support was found for this limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14-22, 137 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 21, the feature of "direct engagement" is not understood.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12, 20-21, 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al., USP 6,669,883 in view of Pins et al., USP 5,229,164 (both of record).

The cited primary reference substantially teaches the basic claimed process of manufacturing a molded dosage form. . The detailed method steps include providing a flowable material by first preparing a composition by including active pharmaceutical ingredients in polymers, the active ingredient in the form of a molecular dispersion in the polymer. The molding machine conventionally includes an upper and lower mold part with a mold cavity inbetween. The molding machine heats the composition to produce a flowable material, and the material is pressed into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Note that the material is extruded, and is thus readable on the claimed step of injecting into a mold cavity.

Please see the abstract, col. 2, lines 1-15; col. 3, lines 5-32, 57-67; col. 7, lines 25-60; the example at col. 12, lines 33-37 and claims 1-7.

The cited primary reference does not teach the claimed steps of cooling and traveling as claimed, nor a nozzle with direct engagement with a molding chamber, per se.

The secondary reference teaches as conventional the newly claimed limitation of molding a dosage form containing a medicament, by injecting through a nozzle into a mold cavity using direct engagement. This method is an improvement in the art as it avoids an additional shaping step. See col. 3, lines 64-68; col. 4, lines 1-10; col. 5, lines 8-10, 39-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include injecting through a nozzle with direct engagement with a cavity as shown in the added reference, when performing the process set forth in the primary reference, for avoiding an additional shaping step.

Note that the primary reference incorporates by reference plasticizing as performed conventionally in the art at col. 3, lines 8-20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of cooling during hardening to solidify the melted material as is well known in the art.

With respect to claims 2-5, 11, note that the heating and cooling performed includes conventional means; it would have been obvious to further include the conventional means claimed for achieving the desired temperature effect, see col. 3, lines 10-15 (cooling by incorporation by reference).

Claim 6, see primary reference at col. 4, lines 25-27.

Claim 7, see primary reference at col. 5, lines 5-10.

Claim 8 and claim 9, see primary reference at col. 5, lines 18-20.

Claim 10, see primary reference at col. 4, line 26.

With respect to claim 12, note that a defect free product is a long-standing felt need in the art of making dosage forms and would have been obvious to include for making an attractive product.

Claim 21, circular paths for rotary tools is conventional in the art and obvious for making similar products.

Claim 137, see primary reference at col. 3, lines 10-13.

Claims 14-19, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al., USP 6,669,883 in view of Voss, USP 6,177,125 (both of record).

The cited primary reference teaches the basic claimed process of manufacturing a solid molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition by including active pharmaceutical ingredients in polymers, the active ingredient in the form of a molecular dispersion in the polymer. The molding machine conventionally includes an upper and lower mold part with a mold cavity inbetween. The molding machine heats the composition to produce a flowable material, and the material is pressed into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Note that the material is extruded,

and is thus readable on the claimed step of injecting into a mold cavity. Please see the abstract, col. 7, lines 25-60; the example at col. 12, lines 33-37 and claims 1-7.

The cited primary reference does not teach the claimed step of placing an insert in the mold cavity prior to injecting or the newly claimed direct engagement feature.

The added reference teaches as conventional a method of making coated tablets that comprise a core, the method further including placing the core or insert in the mold cavity prior to complete molding of the tablet. The detailed steps include providing a coating composition in granulate form, adding a core to the granules and molding the composition into tablet form. One embodiment forms the process in a single step, while additional embodiments partially fill the mold, place the core within the mold and then completely fill the mold to form a coated tablet. Note that the core can be injected. With respect to the newly claimed limitation, note that the added reference teaches direct injection into the tableting material at col. 2, lines 25-30. See also claims 1-21; col. 1, lines 48-57.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add an insert prior to complete molding of the dosage form and to provide direct engagement as claimed, in view of the added reference, when performing the process set forth in the primary reference, for forming an encapsulated tablet directly within the molding cavity. Note that the primary reference prefers a liquid center fill; it would have been obvious to use a non-liquid fill in view of the added reference, for forming an encapsulated tablet in a single process step.

***Response to Arguments***

Applicant's arguments with respect to claims 1-12, 14-22, 137 have been considered but are moot in view of the new ground(s) of rejection. Note that the newly provided art combination fully addresses the claimed limitations.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP 5350548 (of record) is pertinent for showing the apparatus as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 571-272-1206. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Angela Ortiz  
Primary Examiner  
Art Unit 1732

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